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510(K) SUMMARY FOR INVACARE CORPORATION'S 3G TARSYS SEATING SYSTEM

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is K033819.

Date: November 20, 2003

Submitted by: Invacare Corporation
One Invacare Way
Elyria, Ohio 44035-4190

Telephone: 440-329-6356
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Contact Person: Carroll L. Martin, Regulatory Generalist

Trade Name: 3G Tarsys

Common Name: Power wheelchair

Classification Name: Wheelchair, powered

Legally Marketed Predicate Device(s): Invacare Model 2G Tilt/Recliner for Powered Wheelchairs
Invacare Elevating Seat Option ESS6
Motion Concepts TRZ-CG Power Positioning System with Center-of-Gravity Shifting Power Tilt, Recline and Power Elevating Seat

Device Description: The Invacare 3G Tarsys is a battery powered, motorized seating system designed for use with power wheelchairs. The seating system is rated for 300 pounds. Tilt only and recline only versions are rated for 400 pounds

An electrically operated linear actuator drives the tilt and recline functions with weight balance maintained through the stability of the base. The recline function incorporates a mechanical sliding back mechanism to reduce back shear as well as optional power elevating leg rests. The elevate function is driven by an electrically operated linear ball screw actuator mounted in a vertical fashion and allows the seat to be elevated to a maximum of 7" ± .25".

The tilting, reclining and elevating systems are separate modules and are independent of each other. As such, they will be offered as either a complete tilt/recline/elevate system, a combination of tilt/recline, tilt/elevate or as separate tilt only, elevate only or recline only systems depending on the user's needs.

The joystick in conjunction with the Tilt Recline Elevate Control Mechanism (TRECM) and the Invacare MKV EX controller activates the power positioning modules. FDA granted the Invacare MKV EX controller marketing clearance on November 19, 2002 under 510(k) Accession Number K0223589. The Tilt Recline Elevate Control Mechanism can only be used in conjunction with the MKV controller. It connects to the MKV controller by way of an accessory port located on the MKV controller housing.

Safety features include a drive lock-out which prevents the user from driving the power chair while tilted beyond a pre-set limit of 20°. The stability of the 3GTRE was tested in our facility to ensure that the safety of the power wheelchair was not compromised by the addition of the power seating system.

Intended Use: The intended function of the tilt/recline seating system is for repositioning and/or weight shift for pressure relief for individuals who cannot do this independently due to injury or disability. The elevate function is intended primarily to provide powered elevation of the wheelchair seat and user in order to assist the user with daily activities, transfers and general accessibility.

Substantial Equivalence: Products that are substantially equivalent to the Invacare 3G Tarsys are the Invacare 2G Tarsys (K991119, August 19, 1999), the Invacare Elevating Seat Option ESS6 (K013516, December 13, 2001) and the Motion Concepts TRZ-CG Power Positioning System with Center-of-Gravity Shifting Power Tilt, Recline and Power Elevating Seat (K021264, July 30, 2002).

Each of these products are battery powered, motorized seating systems designed for use with powered wheelchairs. Their performance characteristics, power supply and drive mechanisms are similar. The Invacare 3G Tarsys and the Motion Concepts TRZ-CG Power Positioning System with Center-of-Gravity Shifting Power Tilt, Recline and Power Elevating Seat both have the same intended use in that they are intended to aid in the pressure relief of persons confined to a power wheelchair by providing a method of tilting the seat and reclining the back and also to provide powered elevation of the wheelchair seat and user in order to assist the user with daily activities, transfers and general accessibility. The Invacare 3G Tarsys and the Invacare 2G Tarsys have the same intended use in that they are both intended to aid in the pressure relief of persons confined to a power wheelchair by providing a method of tilting the seat and reclining the back. The Invacare 3G Tarsys and the Invacare Elevating Seat Option ESS6 have the same intended use in that they both are intended to provide powered elevation of the wheelchair seat and user in order to assist the user with daily activities, transfers and general accessibility.

The Invacare 3G Tarsys offers an elevating seat option and a tilt/recline option, which makes it different from the Invacare 2G Tarsys and the Invacare Elevating Seat Option ESS6, respectively.

Performance Standards: Although there are no industry or ISO standards for power tilt and recline systems or power elevating systems, Invacare has chosen to test this product to ANSI/RESNA WC/vol.2-1998 or ISO 7176 standards. This product has also been tested to meet the CAL 117 flammability standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Carroll L. Martin
Regulatory Affairs
Invacare Corporation
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P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K033819
Trade/Device Names: Invacare 3G Tarsys
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: May 14, 2004
Received: May 17, 2004

Dear Mr. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033819

Device Name: Invacare 3G Tarsys

Indications for Use:

The intended function of the tilt/recline seating system is for repositioning and/or weight shift for pressure relief for individuals who cannot do this independently due to injury or disability. The elevate function is intended primarily to provide powered elevation of the wheelchair seat and user in order to assist the user with daily activities, transfers and general accessibility. The Invacare 3G Tarsys is rated for a combined user and accessory weight of 300 pounds. The tilt-only and recline only versions are rated for a combined user and accessory weight of up to 400 pounds. The seating system is intended to be used with power wheelchair bases for which it is found to be compatible.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033819